K060617

APR 5 2006

## SECTION F: 510(k) Summary

**510(k) SUMMARY**
This summary of safety and effectiveness information is submitted in compliance with 21CFR807.92.

1. **Application Date:**
   March 6, 2006

2. **Applicant Information:**
   Polymer Technology Systems, Inc.
   7736 Zionsville Road
   Indianapolis, IN 46268
   **Contact Person**: Margo Enright
   **Phone Number**: 317-870-5610
   **FAX Number**: 317-870-5608
   **e-mail:** menright@cardiochek.com

3. **Trade Names:**
   PTS PANELS HDL Cholesterol Test Strips

4. **Description:**
   PTS PANELS HDL Cholesterol Test Strips consist of chemical reagents in dry form. When whole blood is placed on the test strip, only the HDL cholesterol fraction passes through to the reaction layer. The HDL cholesterol reacts with a dried cholesterol reagent to produce color. The HDL concentration is proportional to the intensity of the color developed and is measured by a CardioChek brand analyzer.

5. **Classification Names:**
   Lipoprotein test system
   **Panel:** Clinical Chemistry 75
   **Product Codes**: NAQ, LBR

6. **Facility Address:**
   7736 Zionsville Road
   Indianapolis, IN 46268

7. **Device Classification:**
   Class I (Regulations: 21 CFR 862.1175, 21 CFR 862.1475)

8. **Intended Use:**
   PTS PANELS HDL Cholesterol Test Strips are intended to measure high density lipoprotein cholesterol in whole blood. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.

9. **Reason for 510(k):**
   Device Modification

**10. Predicate Device Information**

The predicate devices for determination of substantial equivalence are:
**Name:** PTS PANELS HDL Cholesterol Test Strips
**Device Company:** Polymer Technology Systems, Inc.
**510(k) Numbers:** K990247 and K993377

**Similarities and Differences between modified PTS PANELS HDL Cholesterol Test Strips and the Predicate Device (unmodified)**

**Similarities Between Predicate and Modified Device**

| Item | Predicates | Modified Device |
|---|---|---|
| **Intended Use** | Intended to measure HDL cholesterol in whole blood. | **Same** |
| **Technology** | Dry chemistry test strip for use with PTS reflectance photometer. | **Same** |
| **Measuring Range** | 25-85 mg/dL HDL Cholesterol | **Same** |
| **Product Storage** | Store with vial tightly capped in a cool dry place at room temperature of 68-86°F. | **Same** |
| **Specimen** | Whole blood from fingerstick or venous blood collected in EDTA or heparin tube. | **Same** |
| **Chemistry Method** | Enzymatic (cholesterol esterase/oxidase) trinder method for cholesterol. | **Same** |
| **Calibration Curve** | Resides on a read-only memory (EEPROM) chip packaged with the test strips. | **Same** |

**Differences Between Predicate and Modified Device**

| Item | Predicates | Modified Device |
|---|---|---|
| **Chemistry Fractionation** | Phosphotungstic acid precipitation method. | Dextran sulfate inhibiting method. |
| **Blood Separation membrane** | Contains glass fiber. | No glass fiber. |
| **Analyzer** | Used on MTM BioScanner (K972669) | Used on BioScanner Plus (K013173 and K014099), which is marketed as CardioChek and CardioChek PA. |

**11. Compliance with Special Controls**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 5 2006

Ms. Margo Enright
Manager of Clinical Affairs
Polymer Technology Systems, Inc.
7736 Zionsville Road
Indianapolis, IN 46268

Re: k060617
Trade/Device Name: PTS PANELS HDL Cholesterol Test Strips
Regulation Number: 21 CFR§862.1175
Regulation Name: Cholesterol (total) test system
Regulatory Class: Class I
Product Code: NAQ, LBR
Dated: March 6, 2006
Received: March 8, 2006

Dear Ms. Enright:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known):

Device Name: PTS PANELS HDL Cholesterol Test Strips

PTS PANELS HDL Cholesterol Test Strips are intended to measure high density lipoprotein cholesterol in whole blood. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.

Prescription Use _X_ AND/OR Over-The-Counter Use _X_
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K060617